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The Need for Safer Medication Use in Pregnancy

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Nearly every pregnant woman has faced a decision about whether or not to take a medication during pregnancy, ranging from over-the-counter antacids for gastroesophageal reflux to prescription medications for life-threatening chronic conditions. Medication use is common during pregnancy; estimates of the prevalence of use during pregnancy of at least one prescription medication range from less than 30% to over 90% of women [1,2]. The safety of use during pregnancy, however, is not always clear because the majority of medications lack sufficient data to appropriately evaluate their teratogenicity until decades after initial marketing [3]. Both acute and chronic medical conditions that are relatively common in reproductive aged women can require treatment during pregnancy, such as infections, cough and cold symptoms, allergies, depression, asthma, thyroid disorders, diabetes, and migraines. However, depending on the timing of pregnancy recognition, women may or may not be aware of their pregnancy when taking medications for these conditions. Medication use during pregnancy impacts two patients, the woman and her developing fetus, and healthcare providers and women are frequently asked to make critical clinical treatment decisions in the absence of sufficient information about the likely impact of the medication on both patients.

Currently there are resources that provide an evaluation of the teratogenic risk associated with specific medications, but these resources are not widely available to women and their healthcare providers as most are available only by subscriptions [4]. Instead, many healthcare providers rely on resources, such as the Physicians' Desk Reference (PDR) and the Food and Drug Administration (FDA) pregnancy categorization as noted in the product label, that do not adequately inform the best medication choice during pregnancy [5,6]. Professional guidance has been developed for some specific conditions or medication types, such as the Committee Opinion from the American College of Obstetricians and Gynecologists on the use of certain antibiotics during pregnancy, the American Academy of Neurology and American Epilepsy Society's guidelines on the management of epilepsy during pregnancy, and the guidelines for the treatment of human immunodeficiency virus

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(HIV) in pregnancy developed by the HHS Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission [7,8][101]. However, there is no systematic and ongoing approach to the development of such guidance for most maternal conditions, and therefore a need for both development of guidance and dissemination to appropriate providers.

Safer medication use during pregnancy also means taking steps to avoid unnecessary exposure to known teratogens in pregnancy. While the teratogenicity of many medications is unknown, there are some medications in use that have been clearly identified as human teratogens such as valproic acid and isotretinoin [8,9]. And, for some known teratogens, use is relatively high among reproductive aged women [10]. This is particularly concerning given the prevalence of unintended pregnancies in the U.S. of 49% [11]. Moreover, most healthcare providers prescribing potentially teratogenic medications in outpatient settings do not provide contraceptive counseling when these medications are prescribed [12].

Some healthcare providers and internet sites provide lists of medications reported to be “safe” for use during pregnancy; however, there are many inconsistencies between the available lists, and the evidence base for labeling many of the medications as “safe” is inadequate [13]. Many sites lack information on how the lists were developed or appropriate citations to peer-reviewed literature. It is unknown whether these “safe” lists actually increase the use of medications during pregnancy, including potentially the use of some medications not really necessary to treat the maternal condition. Most significantly, such lists have the potential to shortcut opportunities for important discussion between a woman and her healthcare provider about the necessity of specific medications during pregnancy given the patient’s full medical profile.

The commonly held assumption of the safety of medications is in contrast to the usual concerns about x-ray exposure in pregnancy. There are little data to support the teratogenicity of diagnostic x-rays at the typical exposure levels [14]. Nonetheless, there is great concern among pregnant women about potential exposure to radiation from diagnostic tests, and reproductive aged women needing x-rays are typically screened for pregnancy in some manner by healthcare providers before diagnostic radiography. There are far less systematic approaches in place to consider the possibility of a current or future pregnancy when making medication treatment decisions. There is a pressing need to increase awareness of medication use in pregnancy as an important public health issue, and to encourage more evidence-based decision making around medication use. Before prescribing medication to reproductive aged women, a conversation about pregnancy, pregnancy intention, and contraception is warranted to adequately assess the true need, and ensure avoidance of unnecessary exposures during pregnancy.

Addressing safer use of medication during pregnancy requires a partnership between public health and clinical medicine with a common goal of improving the health of women and their fetuses/infants. For many relatively common maternal conditions, there is a need to better understand the safety or risk of using specific medication alternatives during pregnancy. While improving the information available for all medications that might be used in pregnancy would be ideal, priority should be given to those conditions and medications

for which more appropriate use is likely to have the greatest public health impact. Some key factors to consider in assessing the potential public health impact include the prevalence of the maternal condition among reproductive aged women, the prevalence of medication use for the maternal condition under consideration, the severity of the maternal condition, and the anticipated necessity of medication for appropriate treatment of the condition. Suspicion of adverse fetal effects based on case reports or animal data might also be considered in assessing the likely public health impact of prioritizing a particular condition.

For example, about 11% of US reproductive aged women reported a major depressive episode within the past 12 months; prescription medication treatment to manage the condition in women with a recent major depressive episode was reported by about 40% of pregnant women and 47% of non-pregnant reproductive aged women [15]. There are several medication options available, and the fetal risk might vary between these options. Furthermore, stopping antidepressant medications during pregnancy is typically not a reasonable option for many women given the necessity of this treatment for maternal health [16]. Similarly, an estimated 8–10% of US reproductive aged women and 8–9% of pregnant women have a current diagnosis of asthma [17]. Although 88% of pregnant women with current asthma reported symptoms during pregnancy, 41% reported no use of asthma medication during pregnancy [17]. Better data on safety or risk of specific asthma medication options during pregnancy could help optimize management of this potentially serious medical condition. However, with no “gold standard” information source to consult regarding treatment decisions for either of these relatively common conditions, clinical uncertainty exists, leading to significant variation in clinical care.

Developing and widely disseminating appropriate guidance for women and their healthcare providers to consider in making medication choices could make a significant positive public health impact. There is the potential to reduce the risk to the fetus by shifting clinical practice towards medications with a lower fetal risk profile, as well as improve the health of women during pregnancy and in their reproductive years by better informing clinical decisions about treatment options for serious medical conditions. The Centers for Disease Control and Prevention (CDC) has recently launched the TR_xeating for Two Initiative as a key step towards safer use of medication during pregnancy. A Task Force model similar to what has been used by the U.S. Preventive Services Task Force is being proposed as the approach to develop and disseminate appropriate evidence summaries assessing maternal, embryonic, and fetal effects of medications used during pregnancy, and would include an evaluation of both the quality and the strength of the evidence assessing these effects [102]. More information about CDC’s work on medications in pregnancy is available at www.cdc.gov/pregnancymedication. Safer medication use in pregnancy can be advanced with a public health – clinical partnership, and this approach has the potential to make an important, positive impact on the health of women and their children.

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